IN THE UNITED STATED DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA

ROBERT E. COLE
ROBERT E. COLE, P.C.
ATTORNEY I.D. NO. 73263
437 CHESTNUT STREET, SUITE 218
PHILADELPHIA, PA 19106
(215) 922-2050

Attorney For Plaintiff

OWEN J. ROGAL, D.D.S., P.C. :
d/b/a THE PAIN CENTER
501-07 SOUTH 12TH STREET
PHILADELPHIA, PA 19147

Plaintiff :

V. : NO. 3:06cv728-MHT

SKILSTAF, INC. :
P.O. BOX 729
ALEXANDER CITY, AL 35011

Defendant :

PLAINTIFF'S PROPOSED WITNESSES

1. Kim Rogal

2. Paul Palmerio, D.O.

3. Owen J. Rogal, D.D.S. (if necessary)

The Pain Center
501-07 South 12th Street
Philadelphia, PA 19147
215-545-2104

4. Dianna Berry
107 Shoreline Drive
Malakoff, TX 75148
903-489-4192

5. Belinda Cotney

6. Robert Johnson

RRI (Risk Reduction Inc.)
P.O. Box 729
Alexander City, AL 35011
800-489-3928

PLAINTIFF'S PROPOSED EXHIBITS

ITEM	ADMINISTRATIVE RECORD/EXHIBIT
1. Medical bills - (1/21/05 - 6/7/05)	Skilstaf 01630-01881
2. Assignment of rights	Exhibit 1
3. Medical notes/reports (1/21/05 - 6/7/05)	Skilstaf 01630-1881
4. Cotney letter of 7/14/05	Skilstaf-00099
5. Pain Center letter of 7/18/05	Skilstaf-00098
6. Counsel appeal letter 9/6/05	Exhibit 2 (collectively)
7. Johnson letter of 9/26/05	Skilstaf-00094
8. Counsel letter of 9/30/05	Exhibit 2 (collectively)
9. RFS peer review literature	Exhibit 3

s/Robert E. Cole
Robert E. Cole, Esquire
Attorney for Plaintiff
Atty. I.D. No. 73263
437 Chestnut Street, Suite 218
Philadelphia, PA 19106
(215) 922-2050
recoleesq6@juno.com

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437 CHESTNUT STREET, SUITE 218
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(215) 922-2050

Attorney For Plaintiff

OWEN J. ROGAL, D.D.S., P.C. :

V. : NO. 3:06cv728-MHT

SKILSTAF, INC. :

VERIFICATION OF SERVICE

Robert E. Cole, Esquire, attorney for plaintiff, hereby verifies that on the 27th day of July, 2007, he electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing as follows:

Amelia T. Driscoll, Esquire
Bradley Arant et al.
1819 Fifth Avenue North
Birmingham, AL 35203-2104

Robert E. Cole, Esquire, attorney for plaintiff, hereby verifies that on the 27th day of July, 2007, he served upon Jeanne L. Bakker, Esquire, attorney for defendant above, a true and correct copy of the foregoing by first class mail, postage prepaid to the following address:

Montgomery, McCracken et al.
123 South Broad Street
Philadelphia, PA 19109

s/Robert E. Cole
Robert E. Cole, Esquire
Attorney for Plaintiff
Atty. I.D. No. 73263
437 Chestnut Street, Suite 218
Philadelphia, PA 19106
(215) 922-2050
recoleesq6@juno.com

RADIOFREQUENCY
RFS

THE PAIN CENTER
is a multi-disciplinary facility of pain specialists, including the fields of anesthesiology, neurology, ENT, physical medicine, clinical neuro-electrophysiology, neuropsychology and musculoskeletal manipulation.

THE PAIN CENTER

TO: Skel S: rcf
Address: Po Bo 429
Alexandria City
Al, 35011

Re: Patient's Name: Dianne Berry
Your Insured: Dennis + Dianne Berry
Claim No. : 464703912

I hereby irrevocably sign to The Pain Center any right, which I may have against any insurer that may be responsible r the payment of medical bills incurred by reason of any treatment by the doctors. Without dimi ishing this assignment, I retain the right to sue any person legally responsible for my injur s and include therein a claim for payment of The Pain Center bills. I understand that I may be responsible for any such bills for which there is no source of insurance benefits for services rend ed prior to April 1, 1990.

I hereby authorize yo to pay directly to The Pain Center, <u>and to no one else</u>, benefits due to me under the terms of my licy, a policy of insurance, which by operation of law makes me an "insured," or by reason o: settlement of verdict, which includes a claim for medical bills.

Payment of The Pa Center invoices within thirty (30) days of your receipt of same, as provided under law, is thorized upon your receipt of The Pain Center itemized statement of account and Attending Ph sicians Report form for services rendered to me. Payment of any amount to The Pain Center as her in directed, in whole or in part, shall be considered the same as if paid by your company to me. I yments include, but are limited to, any proceeds under any insurance policy for primary benef coverage under the Pennsylvania, New Jersey, Delaware or New York automobile insurance la , any proceeds of settlement or verdict awarded for medical bills. I further irrevocably assign The Pain Center the right to bring suit in his own name or in my name for any medical bills for atment by The Pain Center that are not paid within thirty (30) days after submission to my carrier. I declare that I view that any failure of my carrier to pay The Pain Center to be an act of bad faith a I assign any rights which I may have as a result of this bad faith to The Pain Center.

You are directed not deliver benefits herein assigned to The Pain Center to anyone other than The Pain Center, and this irective includes my attorney, who has received a copy of this document. The Pain Center will noti my attorney of any payments received.

I understand that I ca ot revoke this authorization without the prior <u>written</u> consent of The Pain Center, and unl s you receive such written notice of revocation from The Pain Center, this document shall remai egally binding.

PLAINTIFF'S EXHIBIT B

SIGNED Dianne Berry

RRI
Risk Reduction, Inc.
Claims Adjusters and Administrators

July 14, 2005

The Pain Center
501-507 South 12th
Philadelphia, PA 19147

Re: Claims for Ms. Dianna Berry (*****3972)

To Whom It May Concern:

I have reviewed the claims for treatment of Ms. Dianna Berry for the following dates of service: 01/21/05 through 04/29/05. It appears that these claims were for services provided by chiropractors. Please note that the SkilStaf Group Health Plan ("Plan"), a self-insured ERISA plan, applies an annual benefit limit of $1,000 for services provided by a chiropractor. Please also note that the Plan provides such benefits only when there is "documented physical improvement" from that treatment. As the Plan already has exceeded the annual limit for chiropractors' services during 2005 for Ms. Berry, no additional benefits are payable under the Plan for the referenced claims. In addition, no future claims will be covered for any such services administered during 2005.

The annual limitation applies to calendar years. If any new claims for treatment by chiropractors are made in 2006 or later years, please submit those claims at that time with appropriate documentation of the physical improvement resulting from such treatment.

Our records indicate that the Plan has provided benefits totaling $71,911.53 for services provided by chiropractors to Ms. Berry during 2005. As noted, those payments exceed the $1,000 limit on benefits for such services. Therefore, please immediately remit to the Plan at the address indicated above, for my attention, the inadvertent excess previously provided to you in the amount of $70,911.53.

Thank you for your attention to this matter.

Sincerely,

Belinda Cotney
Claims Adjustor

Enclosures

Cc: Ms. Dianna Berry

Skilstaf – 00093

RADIOFREQUENCY
RFS

THE PAIN CENTER
is a multi-disciplinary facility of pain specialists including the fields of anesthesiology, neurology, ENT, physical medicine, clinical neuro-electrophysiology, neuropsychology and musculoskeletal manipulation

THE PAIN CENTER

7/18/05

RRI
Risk Reduction
PO BOX 729
Alexander City, AL 35011

Attn: Belinda Cotney
Claims Adjustor

Re: Dianna Berry

This letter shall confirm our [illegible]nformation concerning the fraudulent letter dated 7/14/05, requesting reimbursement of moneys pa[illegible]thur the policy owned by Dennis Berry and Dianna Berry

At no time did this office bill [illegible]r Chiropractic services.

Dr. Kauffman is a DO
Dr. Palmerio is a DO

NEVER WAS A CHIROPR[illegible]CTOR BILLED FOR!

I demand a retraction letter [illegible] by **Monday 7/25/05 @ 9:00 am.** Your retraction letter can be faxed to 215.923.1012.

If I did not receive your retra[illegible]ion letter by the requested date, I intend to turn your collection efforts over to the Insurance [illegible]ommissioner of Alabama.

Kim R. deOliveira

Cc: Mr. Cole
Insurance Commissione[illegible]raud and abuse
State office bldg.

ROBERT E. COLE, P.C.

LAW OFFICES

LAFAYETTE BUILDING
437 CHESTNUT STREET, SUITE 218
PHILADELPHIA, PENNSYLVANIA 19106

TELEPHONE (215) 922-2050
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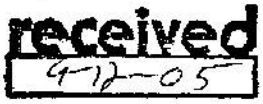

September 6, 2005

SkilStaf, Inc.
P.O. Box 729
Alexander City, AL 35011
ATTN: Robert Johnson

RE: INSURED: DIANNA BERRY/DENNIS BERRY
SS NO. 464-70-3972
D/S: 1/05 TO PRESENT
OUR CLIENT: THE PAIN CENTER

Dear Mr. Johnson;

As you are aware, our office represents The Pain Center with regard to medical bills incurred by above named patient. Per recent conversation with Belinda of your office, please consider this writing "appeal" of your decision (without documentation) not to pay The Pain Center's medical bills incurred by Dianna Berry. Per same, please find enclosed summary of progress reports indicating improvement of the above patient on a per visit basis.

Kindly advise as to when you will be making payment on the bills in question. Please feel free to contact me at your earliest convenience should you have questions or concerns. I look forward to hearing from you regarding this matter. Thank you for your consideration.

Very truly yours,

Robert E. Cole

REC:gk
Enclosures
cc: The Pain Center

Mr. Robert Cole

Re: Dianna Berry

PROGRESS PAIN REPORT
EACH TAKEN FR :M OP REPORTS SUBMITTED CERTFIED WITH
BILL (FORM) TO SKIL STAF

1/21/05 Pre-operative i lerview: Dianna was interviewed and the procedure was explained. An update c the original chief complaints of the patient were: right neck pain 5 out of 10, right sl ulder pain 3 out of 10, right lower back pain 3 out of 10, and headaches are occ pital.

1/28/05 Pre-operative in rview: Dianna was interviewed and the procedure was re-explained. An update o the original chief complaints of the patient were: right neck pain from 5 out of 10 to ! out of 10, right trapezius pain 8 out of 10, and right shoulder pain from 8 o of 10 to 5 out of 10.

2/4/05 Pre-operative int rview: Dianna was interviewed and the procedure was re-explained. An update o the original chief complaints of the patient were: right neck pain from 2 out 10 to 4 ut of 10, right trapezius pain from 8 out of 10 to 4 out of 10, and right shoulder pair from 5 out of 10 to 0 out of 10. Dianna reported that the prior radiofrequency p cedure reduced her right 1st rib pain. She follows sleeping position.

3/18/05 1 of 2 Pre-oper: live interview: Dianna was interviewed and the procedure was re-explained. An u date of the original chief complaints of the patient were: right neck pain 5 out of 10, and right trapezius pain from 4-5 out of 10 to 5 out of 10. Patient states a lot of ly ng around, and lots of sleeping in hotels last month. Dianna reported that the prior diofrequency procedure reduced her right 2nd rib (extreme lateral) pain. She follo sleeping position.

2/18/05 2 of 2 Pre-oper: live interview: Dianna was interviewed and the procedure was re-explained. An u date of the original chief complaints of the patient was: right neck pain 5 out of 10. Dianna reported that the prior radiofrequency procedure reduced her right C7 transverse process pain. She follows sleeping position.

2/25/05 Pre-operative i lerview: Dianna was interviewed and the procedure was re-explained. An updat of the original chief complaints of the patient were: right neck pain 5 out of 10 to out of 10 (constant), and right upper trapezius pain from 5 out of 10 to 3 out of 10 onstant). Dianna reported that the prior radiofrequency procedure reduced her right C4 articular pillar pain. She follows sleeping position

2/11/05 Pre-operative i lerview: Dianna was interviewed and the procedure was re-explained. An updat of the original chief complaints of the patient were: right neck pain from 4 out of 10 (constant) to 3 out of 10 (intermitted), and right upper trapezius pain from 4 o of 10 (constant) to 3 out of 10 (intermitted). Dianna

reported that the prior adiofrequency procedure reduced her right C5 articular pillar pain. She follows leeping position.

2/18/05 Pre-operative in rview: Dianna was interviewed and the procedure was re-explained. An update c the original chief complaints of the patient were: right neck pain from 3 out of 10 to -3 out of 10 (intermitted), and right upper trapezius pain 3 out of 10 (intermitted). atient states doing much better. Dianna reported that the prior radiofrequency p cedure reduced her right C6 articular pillar pain. She follows sleeping positi .

2/25/05 Pre-operative in rview: Dianna was interviewed and the procedure was re-explained. An update c the original chief complaints of the patient were: right neck pain from 3 out of 10 to out of 10 (intermitted), and right upper trapezius pain from 3 out of 10 to 3 out of 1 (intermitted). Patient states pain is less intensity and doesn't linger. Patient ates feel better this week than last. Dianna reported that the prior radiofrequenc procedure reduced her right 2nd rib pain. She is following sleeping position 100%

3/4/05 Pre-operative int view: Dianna was interviewed and the procedure was re-explained. An update c the original chief complaints of the patient were: right neck pain from 3 out of 10 to -5 out of 10, and right trapezius pain 3 out of 10. Dianna reported that the prior adiofrequency procedure reduced her right 3rd rib (lateral) pain. She follows sleep g position.

4/1/05 Pre-operative int view: Dianna was interviewed and the procedure was re-explained. An update c the original chief complaints of the patient were: right neck pain from 2 out of 10 (c nstant) to 2 out of 10 (intermitted), and right upper trapezius pain from 3 o of 10 (constant) to 3 out of 10 (intermitted). Dianna reported that the prior diofrequency procedure reduced her right angle of scapula pain. She follo s sleeping position.

4/15/05 Pre-operative in rview: Dianna was interviewed and the procedure was re-explained. An update c the original chief complaints of the patient was: right upper back/shoulder pain 3 o of 10. Dianna reported that the prior radiofrequency procedure reduced her right mid-s perior scapula spine pain.

4/22/05 Pre-operative in erview: Dianna was interviewed and the procedure was re-explained. An updat of the original chief complaints of the patient was: right scapula 3 out of 10. Di na reported that the prior radiofrequency procedure reduced her right scap a pain.

4/29/05 Pre-operative in rview: Dianna was interviewed and the procedure was re-explained. An update c the original chief complaints of the patient was: right rib pain 3-4 out of 10. Dian reported that the prior radiofrequency procedure reduced her right later scapula spine pain. She follows sleeping position.

5/6/05 Pre-operative inte view: Dianna was interviewed and the procedure was re-explained. An update c the original chief complaints of the patient was: left shoulder pain 4 out of 1 . Dianna reported that the prior radiofrequency procedure reduced her right 6th rib edial pain.

5/13/05 Pre-operative in rview: Dianna was interviewed and the procedure was re-explained. An update o the original chief complaints of the patient was: right shoulder pain from 4 ou of 10 to 3 out of 10. Dianna reported that the prior radiofrequency proced re reduced her right bicep tendon pain.

5/20/05 Pre-operative i terview: Dianna was interviewed and the procedure was re-explained. An updat of the original chief complaints of the patient was: right scapular pain. Dianna eported that the prior radiofrequency procedure reduced her medial superior sc ula pain.

5/23/05 Pre-operative in rview: Dianna was interviewed and the procedure was re-explained. An update o the original chief complaints of the patient was: right shoulder pain 3 out of 1 (intermitted) to a 3 out of 10. Patient states she has soreness on bicep tend n. Dianna reported that the prior radiofrequency procedure reduced her right medial border of scapula pain. She follows sleeping position.

5/25/05 Pre-operative in rview: Dianna was interviewed and the procedure was re-explained. An update o the original chief complaints of the patient were: right shoulder pain 3 out of 10 to a 1-2 ut of 10 (intermittent), right neck from a 3 out of 10 to a 1 out of 10, and right anterior sh ulder pain 1 out of 10. Dianna reported that the prior radiofrequency proced re reduced her right 3rd rib medial pain. She follows sleeping position

5/26/05 Pre-operative in erview: Dianna was interviewed and the procedure was re-explained. An updat of the original chief complaints of the patient was: right headache pain 8 out of 0.

5/27/05 Pre-operative in erview: Dianna was interviewed and the procedure was re-explained. An updat of the original chief complaints of the patient was: right should pain is a 2 out of 0. Patient states that she is feeling better today; she says no more headaches, on over eyes (Intermittent). Dianna reported that the prior radiofrequency proced re reduced her right Blume pain. She follows sleeping position.

6/1/05 Pre-operative inte view: Dianna was interviewed and the procedure was re-explained. An update o the original chief complaints of the patient was: right shoulder pain from 2 ou of 10 to a 1 out of 10. Dianna reported that the prior radiofrequency proced re reduced her right C3 articular pillar pain.

6/3/05 Pre-operative int rview: Dianna was interviewed and the procedure was re-explained. An update o the original chief complaints of the patient was: right neck pain 3 out of 10 (interm ent), and right upper trapezius (intermittent). Dianna reported that the prior radiofrequency procedure reduced her right Blume pain. Patient follows sleeping osition.

6/7/05 Pre-operative int view: Dianna was interviewed and the procedure was re- explained. An update c the original chief complaints of the patient were: left neck pain (stiffness) 4 out of 0), and left shoulder pain (stiffness) 4 out of 10. Patient reports neck stiffness c used shoulder pain.

RRI
Risk Reduction, Inc.
Claims Adjusters and Administrators

September 26, 2005

Mr. Robert E. Cole
Lafayette Building
437 Chestnut Street, Suite 218
Philadelphia, PA 19106

RE: Treatment of Dianna Berry at The Pain Center

Dear Mr. Cole:

I have received your letter dated September 6 regarding this matter. Thank you for the information provided regarding the treatment of Ms. Berry.

Please note that the SkilStaf Group Health Plan ("Plan"), a self-insured ERISA plan, applies an annual benefit limit of $1,000 for services provided by a chiropractor. As the Plan already has exceeded the annual limit for chiropractors' services during 2005 for Ms. Berry, no additional benefits are payable under the Plan for the referenced claims. In addition, no future claims will be covered for any such services administered during 2005.

The annual limitation applies to calendar years. If any new claims for treatment by chiropractors are made in 2006 or later years, the Pain Center may submit those claims at that time.

Please also note that, as previously discussed, the Plan provides chiropractic benefits only when there is "documented physical improvement" from that treatment. The additional material that you provided contains insufficient evidence that Ms. Berry has experienced documented physical improvement from those treatments.

If you have additional information or questions, please let me know.

Sincerely,

Robert C. Johnson

ROBERT E. COLE, P.C.

LAW OFFICES

LAFAYETTE BUILDING
437 CHESTNUT STREET, SUITE 218
PHILADELPHIA, PENNSYLVANIA 19106

TELEPHONE (215) 922-2050
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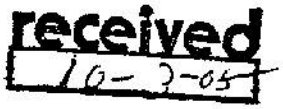

September 30, 2005

SkilStaf, Inc.
P.O. Box 729
Alexander City, AL 35011
ATTN: Robert Johnson

RE:	INSURED:	DIANNA BERRY/DENNIS BERRY
	SS NO.	464-70-3972
	D/S:	1/05 TO PRESENT
	OUR CLIENT:	THE PAIN CENTER

Dear Mr. Johnson;

As you are aware, our office represents The Pain Center with regard to medical bills incurred by above named patient. I am in receipt of your correspondence of 9/26/05 regarding the above. Perhaps you should have read the documentation enclosed with our prior correspondence. *The Pain Center at no point provided Mrs. Berry with chiropractic treatment.* In fact, The Pain Center has never offered said discipline to any patient.

We will be placing this matter into litigation immediately. Thank you for your attention hereto.

Very truly yours,

Robert E. Cole

REC:gk
cc: The Pain Center

Cervicogenic headaches: Radiofrequency neurotomy and the cervical disc and fusion

PEER REVIEWED PAPER

Horst G. Blume, MD, PhD,
Former Clinical Associate Professor,
University of South Dakota,
700 Jennings, Sioux City, Iowa 51105, USA. E-mail: hblume@pionet.net

Please address all correspondence and requests for reprints to the author at the above address.

Clin Exp Rheumatol 2000; 18 (Suppl. 19): S53-S58.

Key words:
Cervicogenic headache, sympathetic chain, sinu-vertebral nerves, radiofrequency neurotomy, C2 medial rami, sub-occipital nerve territory, cervical disc and fusion, cervical discography.

See page S-56 for The Pain Center article on the radiofrequency technique, RFS

C[illegible] *hol- ogy* [illegible] *"cervi- cog*[illegible] *ebated, describe*[illegible] *various researchers. This paper describes the use of radiofrequency neurotomy procedures to relieve cervicogenic headache at several strategic locations. Procedures listed include those to the greater occipital nerve territory, the C2 medial rami, and the cervical discs. Anatomy relevant to the innervation of the disc by way of the sympathetic chain is described and illustrated.*

Methods
Radiofrequency neurotomy procedures were performed following either a successful nerve block in either the distribution of the greater occipital nerve or the C2 medial rami, or after provocative cervical discography. Cervical disc and fusion surgery is being correlated to the nerve supply of the discs and ligaments.

Results
The majority of patients suffering from cervicogenic headaches can be totally relieved for a lifetime, especially if the pain is unilateral. A very, very small percentage of these patients cannot be helped. The remaining sufferers have a considerable reduction in the intensity and frequency of pain.

Discussion
Each of the procedures discussed, or a combination of all of them, can alleviate cervicogenic headaches completely, as is our goal.

Introduction

The location of the sinuvertebral nerves to disc material, as well as their possible role in the pathogenesis of cervicogenic pain, has been a neglected field. Until recently it was not realized that the tiny sinu-vertebral nerves in the outermost layer of annulus fibrosis could be responsible for disc-related pain.

This nerve was called the 'meningeal branch', as illustrated in Pernkopf's Atlas (1), originating distally to the ganglion and returning back through the nerve root canal to supply the dura and meninges.

Mendel (2) identified the primary rami originating proximally to the nerve root and ganglion as a sole supply of the sinuvertebral nerve of the disc and adjacent ligaments. It is therefore important to illustrate these nerve structures to understand the rational for different treatment modalities. A new nerve staining method, the acetylcholinesterase whole-mount method studied in human fetuses, and a more sophisticated microdissection enabled these workers to identify 4 to 6 nerve strands ventrally and 2 strands dorsally, interwoven with the nerve root and its ganglion. These strands originate from the sympathetic chain, the rami communicantes, and in the cervical spine from the perivascular nerve plexus of the vertebral artery. Thick and thin sinuvertebral nerves were exposed which ascend, descend and communicate with the opposite side (dichotomizing). Innervation of the facet joints (zygoapophyseal joint) was not found to be exclusively from the sympathetic trunk. Even though the origin was sympathetic, it contained nociceptive, proprioceptive, vaso-motor and vaso-sensory nerve functions.

We have dissected and exposed these tiny nerve strands interwoven with the nerve root and its ganglion by literally 'lifting up' the third cervical nerve in order to illustrate these sympathetic strands in the nerve root canal. We could not illustrate the ascending, descending and cross communicating sinuvertebral nerve structures in a simplified drawing, but the artist Rex Muller was able to illustrate sinu-vertebral nerves sprouting towards the center of the cervical disc in a disrupted, sequestered disc where the nucleus pulposus has disintegrated (Fig. 1).

Freemont (4) has investigated the inner-

PLAINTIFF'S EXHIBIT

ral region, around the eyes and retro-or-

of C4/5, C5/6 and C6/7 may also cause radiating pain in the shoulder or arm.

If discography reproduces the original pain and visualizes the pathology of the disc, this may enable the appropriate determination of treatment. For instance, discography to the discs, levels C2/3, C3/4 and C4/5, is able to identify which level is responsible for the cervicogenic headaches. Using this diagnostic technique before cervical disc and fusion, we have found an increase in the percentage of the relief from cervicogenic headaches from 52% to 86%. In previous communications we found that using this technique we were able to relieve neck/shoulder/arm pain in 92% and obtain complete relief in 52% of those with cervicogenic headaches (6).

CT scans are not helpful in my experience unless they are done immediately at the discogram for each level separately where the C-arm is combined with the scanner, because the contrast material disappears rapidly out of the epidural space.

Methods of treatment

Radiofrequency to the cervical disc C2/3 and C3/4

The location of the radiofrequency-induced (RF) lesions depends upon the cervicogenic headache with unilateral symptomatology. The approximate sizes of the lesions are 2 mm to 4 mm in diameter and 4 mm in length, and 6 to 8 lesions are made.

When performing the radiofrequency procedure, only one direction is possible. After making a number of lesions at or near the center of the disc, the needle is advanced to the outer layer of the posterior lateral quadrant. In recent cases we have been advancing the RF needle through the outer layer of the annulus fibrosis entering the nerve root canal, making up to 3 or 4 RF lesions to interrupt the interwoven network of 4 to 6 strands of the sympathetic nerve structures ventral and 2 of the strands dorsal to the nerve root and some of the nociceptive C-fiber activity within the C3 nerve root.

In a desiccated or disrupted disc the sinuvertebral nerve grows and sprouts not only into the inner one-third of the annulus fibrosis, but extends to the disrupted nucleus pulposus in lumbar regions (4), suggesting by inference the importance of the pathogenesis of neck pain and cervicogenic headaches, because these elongated nerve structures can also be stretched, squeezed, pulled, compression, pinched or twisted.

If this procedure has to be repeated, after at least one month of complete relief of cervicogenic headaches, additional lesions are made by changing the direction of the pathway of the RF needle by a few degrees (Fig. 3). The same procedure can be done bilaterally, but during the same sitting. In the diagram we retained the previous drawing showing the distribution of the so-called primary rami originating from the nerve root (2); however recent research by Groen (3) calls into question the existence of the primary rami.

The same procedure can be performed at the disc level at C3/4 except that the needle is not advanced into the nerve root canal because of the important motor function of the C4 nerve root. Six to eight lesions are made at 80°C for 3 minutes at a time, producing lesions 2 to 3 mm in diameter and 4 mm in length. Figure 3 illustrates the primary rami (2) and the sympathetic nerve supply (3), as well as the sprouting of the sinuvertebral nerves to the center of the disrupted and desiccated disc (4). The RF needle position is shown with the lesions outlined in red, extending into the C2/3 nerve root canal

Suggested Corrected Nerve Supply to the Cervical Intervertebral Disc and Ligaments

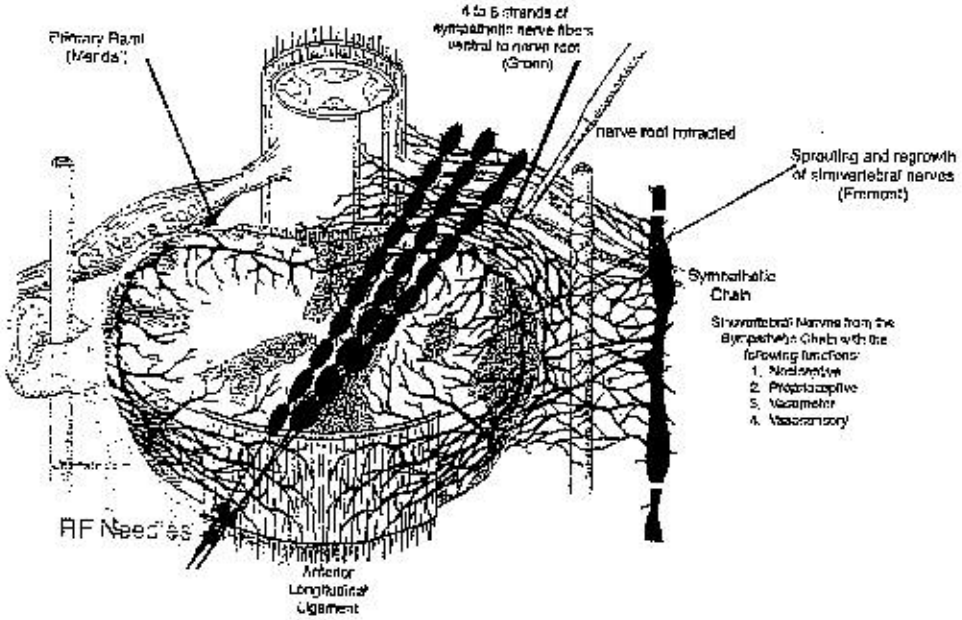

Fig. 3. Nerve supply to the intervertebral disc. Left side shows the distribution of the primary rami (Mandel) as the sole nerve supply to the disc is incorrect. The right side demonstrates innervation of the disc solely by sympathetic strands from the sympathetic chain, rami communicantes and perivascular plexus. If this procedure has to be repeated, additional lesions are made by changing the direction of the pathway of the RF needle by a few degrees, unilaterally or bilaterally.

prior to making RF lesions between the uncinate processes, incorrectly called the "joints" of Luschka. Notice that there are three needle pathways demonstrating that double or triple lesions may be performed in order to provide maximum benefit. We cannot denaturate the entire sympathetic nerve supply to the disc, as this is technically impossible. If relief lasts for several months, additional lesions can be made by changing the direction of the RF needle a few degrees to obtain a new pathway, as outlined in Figure 3. In this drawing we preserved the previously drawn nerve supply to the discs from the primary rami of the nerve root which is now incorrect.

Unlike Shiitjer (7), we found that more than one lesion in the disc is necessary for the reduction or relief of cervicogenic headaches at the level of either C2/3 or C3/4. (It should be kept in mind that the cervical discs of C4/5, C5/6 and C6/7 could also be responsible for the cervicogenic headaches.)

Before advancing the needle to the C3 nerve root, electrical stimulation is applied. Many patients experience a tingling sensation at the head/neck junction, upper to mid-cervical region, and the superior border of the trapezius. Once the needle is advanced to the nerve root canal there is usually a slightly greater degree of minimal muscle contraction of the trapezius, causing the head to turn ipsilaterally and is related to the monopolar stimulation.

Results of RF to the cervical disc C2/3 and C3/4

The RF lesions to these structures resulted in complete relief of cervicogenic headaches in a limited number of patients for a few months. Rarely did the relief last up to 6 months unless the lesion was extended into the C2/3 nerve root canal with denaturation of up to 8 strands of the sympathetic nerve structures.

A detailed analysis of 24 cases of patients undergoing radiofrequency of the C2-3 and C3-4 discs for cervicogenic headache has previously been described. Four patients had the RF procedure at C2-3, three at C3-4, two at both levels, and all 9 patients reported complete relief for 2 to 6 months from the date of the procedure. Three had 70% relief, 5 had 50% relief and 3 had a 30% decrease of cervicogenic headache pain. Four had no results. Six of the 24 patients required cervical disc and fusion surgery at the same levels where the radiofrequency was done. The 20 cases where we made lesions within the nerve root canal had a follow-up of 9 months but we have not statistically analyzed these cases because of the short follow-up duration.

The side effects to these lesions in the C2/3 nerve root canal were temporary hypanalgesia, or hypesthesia of the ear lobe ipsilaterally either in the upper or lower ear lobe with the exception of the external auditory meatus, tragus, concha and the inner portion of the anthelix basically involving the helix lobule. A very slight unsteadiness without nystagmus or ataxia was observed for 1 to 2 weeks in only 2 patients, most likely related to temporary dysfunction of some of the cervical musculature. We perform all radiofrequency procedures using Owl and Radionic systems and their accessories.

Cervical disc and fusion surgery

During the cervical discectomy and fusion procedure, a number of sympathetic end fibers of the sinuvertebral nerves that have sprouted into the central portion are removed. The importance of this procedure is to remove all of the disc tissue adjacent to the nerve root, unroofing the nerve root canal, avoiding injury to the sympathetic strands interwoven with the nerve root and ganglion, and separating the sinu-vertebral nerves from sympathetic strands that remain untouched. By removing some anterior and all posterior disc elements, one interrupts sympathetic nerve structures that are ascending, descending and crossing contra-laterally. The lateral, anterior and mid-portion of the disc remains intact with its sympathetic network and helps to maintain stability.

In some cases the posterior longitudinal ligament is absent because over the years it has been eroded and the disc with its sinuvertebral nerves is directly in contact with the dura and nerve root sleeve. If the posterior longitudinal ligament is intact, it does not extend over or protect the nerve roots. Instead it covers basically two-thirds of the posterior central portion of the spinal canal with its disc. Therefore, if one is performing a surgical procedure where the posterior longitudinal ligament is still present, one must remove it or use bipolar coagulation to destroy as many sympathetic fibers with their proprioceptive, nociceptive, vasomotor and vaso-sensory function as possible. By keeping the ligament intact, one may increase the stability of the spine. If consolidation occurs it will reduce and alleviate the pain from mechanically squeezed sympathetics in the remaining disc, adjacent ligaments and facet joints. We re-emphasize that these nerves to the joints have not been confirmed to be exclusively supplied by the sympathetics.

We have performed over 700 cervical disc and fusion surgeries for neck/shoulder, neck/shoulder/arm pain and cervicogenic headaches. When an additional second or third disc is removed we have found the relief of neck/shoulder/arm pain to be up to approximately 92%, and in 86% the complete relief of cervicogenic headaches was obtained.

Radiofrequency denaturation of the C2 medial rami

RF to the C2 medial rami, its sympathetics and unmyelinated nerve structures to the obliquus capitis inferior, rectus capitis major, semi-spinalis and atlantic muscle groups was first performed by Rogal (8) and Francis (9). We found that about 50 lesions are needed to denaturate the unmyelinated nerves of the interspinal muscle between C1/2 and C2/3. Indications for this procedure include a trial nerve block with relief of cervicogenic headache lasting from 6 hours to several days (Fig. 4).

One hundred patients with the diagnosis of cervicogenic headache were chosen for this procedure. Thirty percent were male and 70% were female, with an age range of 27-84 years. A total of 110 procedures were performed. Forty-nine patients had one C2 rami radiofrequency procedure performed. Twenty-five patients had the procedure performed more than once. The number of lesions ranged from 18 to 52 during a single procedure, unilaterally.

Pain relief ranged from 100% in 43 patients, to greater than 90% in 7 patients,

greater than 80% in 5 patients, and greater than 70% in 7 patients, while 11 patients had pain relief ranging from 25% to 60%. Twenty-one patients had no relief of pain.

Radiofrequency to the greater and tertiary occipital nerve territory:

RF lesions were made to the terminal sensory, sympathetic and unmyelinated nerve structures of the relevant muscle attachments: semispinalis capitis, rectus capitis posterior major, rectus capitis posterior minor, and obliquus superior as outlined in the figure. This procedure accomplished complete relief of cervicogenic headaches in over 80% of 750 patients observed for over 30 years. Despite the fact that we have made up to 50 unilateral radiofrequency lesions, no permanent sensory deficit in the distribution of the greater occipital nerve was found. Success was defined by lack of recurrence for 6 months.

In one case a 16-year-old female suffered from constant unilateral headaches for 4 years after an accident while playing volleyball. This patient was severely limited in activities of daily living, being confined to bed in a dark room with an ice pack on her head around the clock. Numerous nerve blocks to the nerve structures of the facet joints from C1 to C5 including nerve blocks to the C2 nerve root were of no benefit. Numerous so-called occipital nerve blocks were done with temporary relief for 2 days. A nerve block to the medial rami of C2 with its unmyelinated nerve structures was of no benefit. Fifty-three radiofrequency lesions made to the greater and tertiary occipital nerve territory and unmyelinated nerve structures relieved all of her pain.

Indication for the RF neurotomy procedure (Fig. 5) in the occipital nerve territory requires lack of prior response to other procedures, as well as relief from a suboccipital nerve block of 10 cc of 4% Marcaine mixed with 80mg of Depomedrol fanning out in six different directions over the occiput unilaterally.

Discussion

We stress the importance of trying conservative measures and traditional blocks prior to using this technology. Only in

RF Neurotomy procedure to the Medial Rami and Unmyelinated Nerve Structures at the C2 Spinous Process

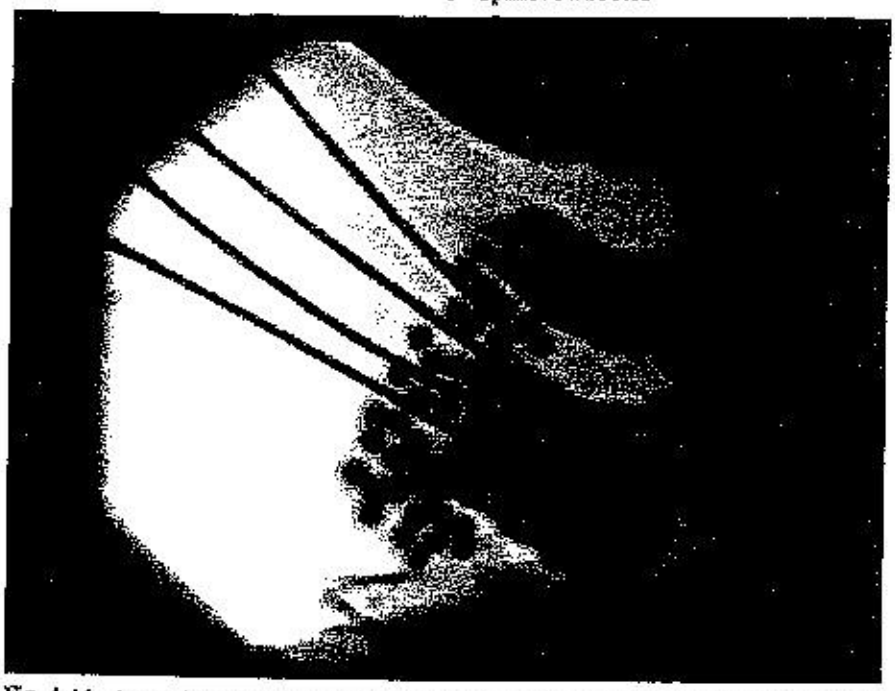

Fig. 4. Muscles attached at the C2 spinous process are the semispinalis, greater posterior rectus, inferior oblique and interspinal muscles that are located between the C1/2 and C2/3 spinous processes.

Cervicogenic Headache: Radiofrequency Neurotomy Procedure

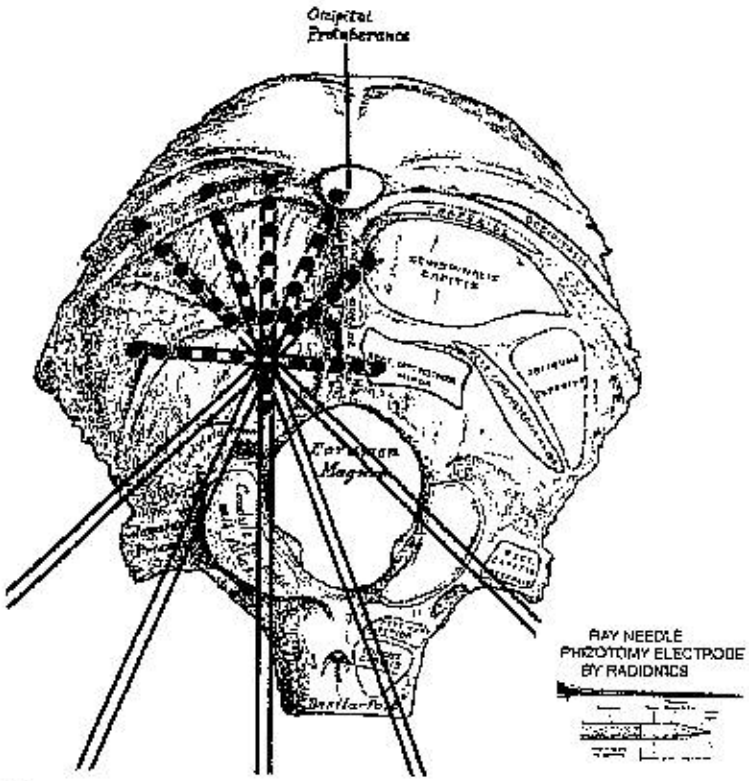

Fig. 5. Schematic drawing of the positions of the thermoelectrodes in 7 different directions in relation to the occipital bone on the left side and this demonstrates the relationship of the muscles shown on the right side. Radiofrequency lesions are made along the tract within the pathway of the thermoelectrode represented by the red dots. Additional lesions are made by withdrawing the needle 5 mm at a time. The average number of lesions is around 50 without severing the function of the greater occipital nerve.

cases of refractory pain are these measures to be employed. We prefer a graduated approach, moving from one method to the next as outlined above.

We also cannot sufficiently stress the need for a careful history and examination to distinguish between tension headaches and unilateral and bilateral cervicogenic disorders. A statistical analysis of all of these cases is being prepared, especially where we have controls where limited RF lesions made within the disc can be compared with lesions within the nerve root canal.

Acknowledgement

The author wishes to thank Monica Ensinger for her very hard work in the production of this paper.

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OCT 20 1989

Formal Review Decision
in the Appeal of
Claudia E. McClaine, SSN: 006-32-0474
a CHAMPUS Beneficiary

This Formal Review is authorized by chapter 10 of the Department of Defense Regulation 6010.8-R (DoD 6010.8-R), which implements chapter 55 of Title 10, United States Code. The patient is appealing the denial of CHAMPUS cost-sharing for radiofrequency thermoneurolysis provided on March 10 and April 27, 1987, costing approximately $3,000.00. The initial determination and Reconsideration decision denying the cost-sharing were made by the CHAMPUS Fiscal Intermediary, Blue Cross and Blue Shield of South Carolina.

In issuing this decision, I have reviewed and considered the CHAMPUS records, additional information and argument presented by the appealing party, any additional documentation obtained by OCHAMPUS, and the statutory and regulatory authorities governing CHAMPUS. Following this review, I have determined that CHAMPUS cost-sharing can be approved for the radiofrequency thermoneurolysis as this care was medically necessary and appropriate within the meaning of DoD 6010.8-R.

FACTUAL BACKGROUND

This case involves the 50-year-old dependent spouse of a retired Uniformed Service member. The patient was diagnosed with chronic bilateral temporal tendonitis, Ernest syndrome, right side. On March 9, 1987 and April 27, 1987, as an outpatient, she underwent Radiofrequency generator thermoneurolysis to denervate sensory fibers in the insertion of the left stylomandibular ligament and radiofrequency generator thermoneurolysis to denervate the deep temporal nerves sensory fibers in the insertion zone of the left temporal tendon of the coronoid process of the mandible.

The fiscal intermediary initially and at reconsideration denied claims for the treatment provided on March 9, 1987, and partially cost-shared the treatment provided on April 27, 1987. Subsequently, they notified the beneficiary that the claims had been cost-shared in error since this was an experimental procedure, and recoupment was requested. The beneficiary filed a timely request for formal review on October 15, 1988.

ISSUES AND FINDINGS OF FACT

AUTHORITY

CHAMPUS benefits are authorized by Congressional legislation incorporated in chapter 55 of title 10, United States Code, and implemented by the Secretary of Defense and the Secretary of Health and Human Services in the Department of Defense Regulation 6010.8-R. Specific regulation provisions pertinent to this case are set forth below.

Chapter 4, subsection A.1., states that subject to all applicable definitions, conditions, limitations, or exclusions specified in the Regulation, the CHAMPUS Basic Program will pay for medically necessary services and supplies required in the diagnosis and treatment of illness or injury, including maternity care and well-baby care.

Chapter 2, section B., defines "medically necessary" in part, as the frequency, extent, and types of medical services or supplies which represent appropriate medical care and that are generally accepted by qualified professionals to be reasonable and adequate for the diagnosis and treatment of illness, injury, pregnancy, and mental disorders or that are reasonable and adequate for well-baby care.

Chapter 2, section B., defines "appropriate medical care," in part, as that medical care where the services performed in connection with the diagnosis or treatment of disease or injury, pregnancy, mental disorder, or well-baby care are in keeping with the generally accepted norms for medical practice in the United States and where the authorized individual professional provider rendering the medical care is qualified to perform such medical services by reason of his or her training and education and is licensed or certified by the state where the service is rendered or appropriate national organization or otherwise meets CHAMPUS standards. The definition also specifies that the medical environment in which the medical services are performed is at the level adequate to provide the required medical care.

Chapter 4, subsection G.1., states that services and supplies that are not medically or psychologically necessary for the diagnosis or treatment of a covered illness or injury, for the diagnosis and treatment of pregnancy, or for well-baby care are specifically excluded from coverage under the CHAMPUS Basic Program.

Chapter 10, subsection A.3., states that the burden of proof is on the appealing party to establish affirmatively by substantial evidence the appealing party's entitlement under law and this Regulation to the authorization of CHAMPUS benefits or approval as an authorized provider. Any cost or fee associated with the production or submission of information in support of an appeal may not be paid by CHAMPUS.

Chapter 4, subsection C.1., states that "Benefits may be extended for those covered services described in this section C that are provided in accordance with good medical practice and established standards of quality by physicians or other authorized individual professional providers. Such benefits are subject to all applicable definitions, conditions, exceptions, limitations and/or exclusions as may be otherwise set forth in this or other chapters of this Regulation."

Chapter 2, section B., defines "experimental," in part, as medical care that is essentially investigatory or an unproven procedure or treatment regimen (usually performed under controlled medicolegal conditions) which does not meet the generally accepted standards of usual professional medical practice in the general medical community. Use of drugs and medicines and devices not approved by the Food and Drug Administration for general use by humans (even though approved for testing on human beings) is also considered to be experimental. However, if a drug or medicine is listed in the U.S. Pharmacopeia or the National Formulary and requires a prescription, it is not considered experimental even if it is under investigation by the U.S. Food and Drug Administration as to its effectiveness.

Chapter 4, subsection G.15., excludes services and supplies not provided in accordance with accepted professional medical standards; or related to essentially experimental or investigatory procedures or treatment regimens.

Chapter 4, subsection G.61., excludes all services and supplies related to a noncovered condition or treatment.

Chapter 4, subsection G.71., notes that the fact that a physician may prescribe, order, recommend, or approve a service or supply does not, of itself, make it medically necessary or make the charge an allowable expense, even though it is not specifically listed as an exclusion.

ISSUE: Were the radiofrequency generator thermoneurolysis for treatment of the TMJ capsular neuralgia performed on March 9 and April 27, 1987, considered at that time to have been investigational/experimental and therefore non-covered surgery under the CHAMPUS Program?

Experimental is defined by the regulation as medical care that is essentially investigatory or an unproven procedure or treatment regimen (usually performed under controlled medicolegal conditions) which does not meet the generally accepted standards of usual professional medical practice in the general medical community. The CHAMPUS Policy Branch conducts research of literature in the appropriate fields before making policy decisions for CHAMPUS. The policies made are continually

reviewed and updated with changes. The research consists of peer opinion as well as literature and current research reports on the subject.

In response to inquiry made to the OCHAMPUS Office of Program Development, it was stated:

> Ernest Syndrome is defined as: A group of symptoms resulting from a stretch injury of the stylomandibular ligament; i.e., of the fibers which attach one end of the stylomandibular ligament to the mandible, the bone of the lower jaw.
>
> Based on the literature submitted by Doctor Ernest and on the opinions of medical professionals, radiofrequency generator thermoneurolysis to denervate the deep temporal nerve fibers at the insertion of the temporamandibular ligament is a viable and medically acceptable procedure. The alternative to denervation is the more invasive surgical severing of the ligament. Surgical severing of the ligament in an inpatient procedure which is more costly and requires a longer period of recovery for the patient.

The following organizations were contacted concerning this procedure: The American Academy of Oral and Maxillofacial Surgeons, The American Academy of Dental Electrosurgery, The American Academy of Dental Practice Administration, and the American Academy of Head, Neck and Face Pain. Also contacted was Doctor Brendon Stack, President, of the American Academy of Head, Neck and Face Pain. Doctor Stack is most familiar with the Ernest Syndrome and the treatment methodology utilizing radiofrequency generator thermoneurolysis. Doctor Stack reported that the other method of treatment for the Ernest Syndrome, namely, severing of the stylomandibular ligament, is more intrusive and more costly. Doctor Ernest uses scientific principles in ruling out temporomandibular joint syndrome, temporal tendon syndrome, stylohyoid ligament syndrome, hyoid bone, elongated styloid process, sympathetic cervical ganglia, omohyoid muscle, cervical spine and brachial plexus: For each of these disorders, there is a distinct and separate source of pain, thus by deadening the suspected sources of pain, the disorders can be ruled out one by one.

Destruction of nerve by radiofrequency generator thermoneurolysis is a procedure used in the alleviation of chronic myofascial pain by denervating the stylomandibular ligament when the cause of pain is due to an abnormality of that ligament. Research has shown that radiofrequency thermal lesions when applied to peripheral nerves, have the effect of selectively destroying small nerve fibers while at the same time retaining the larger nerve fibers. In clinical application this has had the effect of eliminating abnormal pain and triggering functions, yet preserving normal tactile sensation for the patient.

As documented by Doctor Ernest, the costs involved in the surgical severing of the ligament are the inpatient hospital fee of $3,199.66 plus the surgeon's fee of $1,200.00 for a total of $4,399.66. By using the radiofrequency generator, the costs are: The hospital outpatient fee of $750.00 and his surgery fee of $750.00 for a total of $1,500.00, resulting in a significant savings using the radiofrequency generator.

In order to obtain an expert medical opinion as to the medical necessity of the surgery, the entire case file was reviewed by the OCHAMPUS Medical Director. Following his review of the case file it was his opinion that the denervation of the stylomandibular ligament by radiofrequency generator was medically necessary and appropriate for this patient's diagnosis.

The OCHAMPUS Policy Manual is being revised to reflect CHAMPUS benefits are available for this procedure, under limited conditions, effective December 4, 1986.

After reviewing the case file, correspondence from the Office of Program Development and from Doctor Ernest, and information supplied by Doctor Brendon Stack, President of the American Academy of Head, Neck and Face Pain, as well as the opinion of the CHAMPUS Medical Examiner, I find that the destruction of nerve by radiofrequency generator thermoneurolysis is no longer considered experimental or investigational.

FORMAL REVIEW DECISION

This decision concludes that the destruction of nerve by radiofrequency generator thermoneurolysis performed on the patient on March 9 and April 27, 1987, as well as all related services and supplies provided in connection with this treatment are no longer considered investigational or experimental and are therefore a CHAMPUS benefit when found to have been medically necessary and appropriate. In this case, I have determined that CHAMPUS cost-sharing can be approved for this treatment and related services and supplies, as this care was medically necessary and appropriate in light of the beneficiary's diagnosis.

APPEAL RIGHTS

Since this is a fully favorable decision, further appeal rights are not applicable.

E. Templer

Evie Templer
Appeals and Hearings Analyst
Office of Appeals and Hearings

The use of radiofrequency lesions for pain relief in failed back patients

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Key words Failed back – Pain – Nerve pathways – Radio frequency lesions

Summary If conservative measures fail in the treatment of the failed back patient and if there is no indication for further surgery, interruption of nerve pathways conducting noxious stimuli may be attempted. The indication for such treatment is made on the result of a series of prognostic blocks analysing the conduction pattern of noxious stimuli. A new technique is described to interrupt the grey communicating ramus, conducting afferent fibres from the anterolateral and anterior parts of the annulus fibrosus. Results indicate a discrepancy between the result of radiofrequency lesions and the outcome of prognostic blocks. The discrepancy is more pronounced in failed back patients. Treatment with radiofrequency lesions is well tolerated and it has few adverse effects. It has a measure of success in a group of patients who are very difficult to manage otherwise.

Introduction

After back surgery, such as laminectomy or fusion, some patients continue to have pain. The cause of failure probably varies from patient to patient. It may have nothing to do with the operation, the preoperative diagnosis having been either wrong or incomplete. On the other hand the operation may have brought a new element into the pain pattern. A new source of pain may have been created, such as pain emanating from a more cranial level after a technically successful fusion. Adhesions and scar tissue may form around the exiting segmental nerve, or there may be real iatrogenic sequelae such as deafferentation pain due to surgical rhizotomies or to accidental injury to a nerve during operation.

Whatever the cause of failure, these patients as a group are more difficult to manage than the non-operated chronic back patient. They tend to have a more complicated pattern with pain emanating from various sources. The outcome of every single form of treatment tends to be more uncertain and psychological factors tend to be more prominent.

Management essentially does not differ from the management of the non-operated chronic back pain patient. The accent is on conservative measures which understandably should always prevail when successful. Surgery may be considered if there is a clear anatomical abnormality and preferably if there is reasonable proof that this abnormality is responsible for the pain.

If both these modalities fail to relieve the pain a radiofrequency lesion is one of the available options. The aim of such a lesion is to reduce the input of noxious stimuli into the cord. Attempts to do this date back to 1971 when Rees[1] described a technique to cut the posterior primary ramus percutaneously with a special knife blade. This was a blind method not using radiological control. A more sophisticated method using a radiofrequency probe was later developed by Shealy.[2] Uematsu *et al.*[3] described a technique for a percutaneous selective radiofrequency lesion of the dorsal root to relieve radicular pain. This technique was later modified by Sluijter and Mehta.[4]

Since the early 1970s, when radiofrequency lesions for back pain were introduced, there have been new developments. There were improvements of a technical nature. The superior quality of C-arm image intensifiers now permits the development of more sophisticated procedures. Likewise the advent of thermocouple temperature measurement in radiofrequency probes has been an important contribution. All this has permitted the refinement of already existing methods such as a percutaneous partial rhizotomy, and also the development of new techniques such as the radiofrequency (RF) lesion of the communicating ramus which is described for the first time in this article.

Nerve supply of the lumbar spine

The reader is referred to excellent articles on this subject in Refs 5–7. Since some knowledge of the anatomy is essential for a subject such as this a short summary follows.

The posterior compartment of the lumbar spine is innervated by the posterior primary ramus of the segmental nerve. This nerve branches off the segmental nerve immediately after it exits from the foramen and curves posteriorly in a groove formed by the superior articular and transverse processes. It divides into a medial and lateral branch. The medial branch innervates the posterior joints in such a way that each joint is served by at least three segmental levels.

The anterior aspect of the dura and the posterior longitudinal ligament are innervated by the sinuvertebral nerve. This nerve is formed just outside the intervertebral foramen from contributions from the main segmental nerve and from the grey ramus communicans. It then runs back into the spinal canal through the foramen, running somewhat cranial to the disc.

There has been little interest in the annulus fibrosus as a source of pain. The outer layers, however, are richly innervated.[8] The innervation has been eminently described by Bogduk.[7] The posterolateral part is innervated by small branches of the anterior primary ramus. The lateral and anterolateral part are innervated by rami of the grey ramus communicans. These are afferent fibres which are not part of the sympathetic system but which are travelling with it on their way to the dorsal root ganglion, where their cell bodies are. The same can be said for branches of the sympathetic chain which innervate the anterior part of the annulus fibrosus and the anterior longitudinal ligament. These last fibres too then reach the dorsal root ganglion via the communicating ramus (Figures 1 and 2).

Indications for radiofrequency lesions

Before making a radiofrequency lesion a detailed diagnosis as to the cause of pain is indispensable. Unfortunately this may not be revealed either by physical examination or by diagnostic procedures such as plain X-rays, myelography or computerized tomography (CT) scan. The distribution of pain is not pathognomonic for any structure in the back causing pain. Pain referral tends to overlap, both from structures within one segment[9] and from structures in different segments.[10] Paravertebral tenderness is an unreliable sign. It may indicate involvement of the posterior joints but it may also be prominent in patients with true radicular pain or with pain emanating from the annulus fibrosus. Leg pain may be referred from mechanical structures in the back and impaired straight-leg raising does not necessarily mean that a segmental nerve is irritated.[5] Diagnostic procedures may at best reveal morphological abnormalities but these are not necessarily the cause of the pain. The indication for a radiofrequency lesion should therefore never be made on an anatomical diagnosis but on the result of an analysis of the conduction pattern of noxious stimuli with a series of prognostic blocks.

The indication to explore the possibilities of radiofrequency lesions is continuing pain which is unrelieved and unrelievable by other methods on the one hand, and which might possibly respond to radiofrequency lesioning on the other. When making this decision there are usually four points to keep in mind:

1. Conservative therapy should have been fully explored. This is true when deciding on any form of invasive treatment and radiofrequency lesions are no exception.

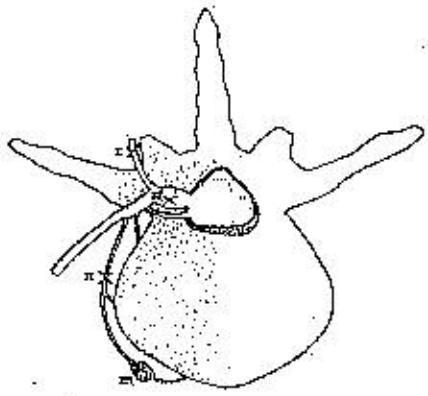

Figure 1 Schematic drawing of a cross-section of the lumbar spine showing the innervation of the various structures. Radiofrequency lesions can be made in: I the posterior primary ramus; II: the communicating ramus; III: the sympathetic chain; IV: the dorsal root ganglion.

Figure 2 Schematic drawing of the lumbar spine in a 20° oblique projection. I: Percutaneous facet denervation; II: RF lesion of the communicating ramus; III: RF sympathetic block.

2. Further surgery may be indicated, but if there is any doubt about the indication there is no harm in trying radiofrequency lesions first. The surgeon is not hampered in any way if the patient is eventually operated. However, subsequent treatment with radiofrequency lesions is less likely to succeed following surgery.
3. Prognostic blocking should only be undertaken if there is a chance at least that the result may ultimately be followed by treatment. There is therefore no point in doing prognostic blocks in patients with a diagnosis of denervation pain or extensive arachnoiditis with accompanying sensory loss.
4. Psychological factors should be taken into account, although it is very difficult to apply strict criteria. Preoperative psychological tests have a measure of predictive value but the result has only circumstantial value in an individual patient. Moreover these tests may normalize after successful somatic treatment.[11] Macnab[12] stresses that a diagnosis of 'psychogenic pain' is a positive diagnosis, and that it should not be made on exclusion of other findings. Such a positive diagnosis can sometimes be made on grounds of inappropriate signs and symptoms,[13] but even this should be done with great care.

Prognostic blocking

There are two types of functional tests to analyse the conduction pattern of noxious stimuli: prognostic blocks and electrostimulation. At first sight prognostic blocks seem to be the ideal method. There are, however, some pitfalls which one has to be aware of. First, injected fluids have a nasty habit of spreading elsewhere. A segmental nerve block, for instance, may easily spread into the epidural space. Prognostic blocks should therefore always be done under fluoroscopic control with the use of a water-soluble contrast to monitor the spread of the injected fluid, and small quantities should always be used, to ensure optimal selectivity.

Secondly, one should realize that prognostic blocking is different from checking electrical wiring. Prognostic blocks have an additional time dimension. During the time of action of a prognostic block there is a complete cessation of afferent inflow from a source for a short period, whereas after a radiofrequency block there is a partial reduction of input for a protracted period of time. This limits the value of prognostic blocks as a predictor for the outcome of radiofrequency lesions. The sudden impact of a prognostic block may temporarily disrupt existing conditions. Thus, if there are two sources of pain and one source is blocked, there may temporarily be such a decrease of input into the dorsal horn that there is complete relief of pain and the other source is masked.

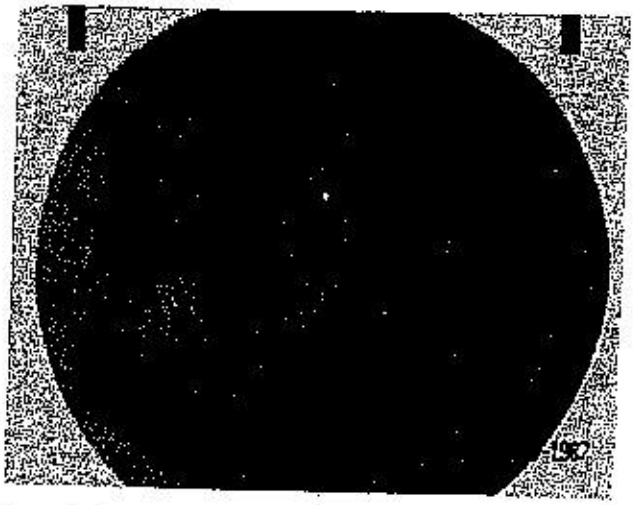

Figure 3 Prognostic facetal block. Ten-degree oblique projection.

Finally, when performing prognostic blocks one should realize that deafferentation pain may be effectively blocked and that one should be careful not to derive wrong conclusions from such a phenomenon.

Electrostimulation is useful to determine the accurate segmental level in true radicular pain. The patient is usually able to recognize the distribution pattern of the sensations evoked by a 50 Hz current through an electrode placed near the segmental nerve. Even so, this is an auxiliary method, and it should always be followed by a prognostic block to confirm the evidence.

It is helpful to follow a systematic sequence when performing prognostic blocks. Since so-called radiating pain may in fact be referred pain from a mechanical structure it is preferable to block the input from possible mechanical sources of pain first. The sequence is further governed by the possible consequences. A prognostic block corresponding with a procedure with the lowest morbidity and complication rate comes first. This results in the following sequence:

A: PROGNOSTIC BLOCKS FOR MECHANICAL PAIN
1. Posterior joint block (Figure 3)
2. Communicating ramus block at L4 and L5 consecutively (Figure 4).
3. Sympathetic block at L4.

B: PROGNOSTIC BLOCKS FOR RADICULAR PAIN
4. Exiting segmental nerves L4, L5, S1 and S2 as indicated (Figure 5).

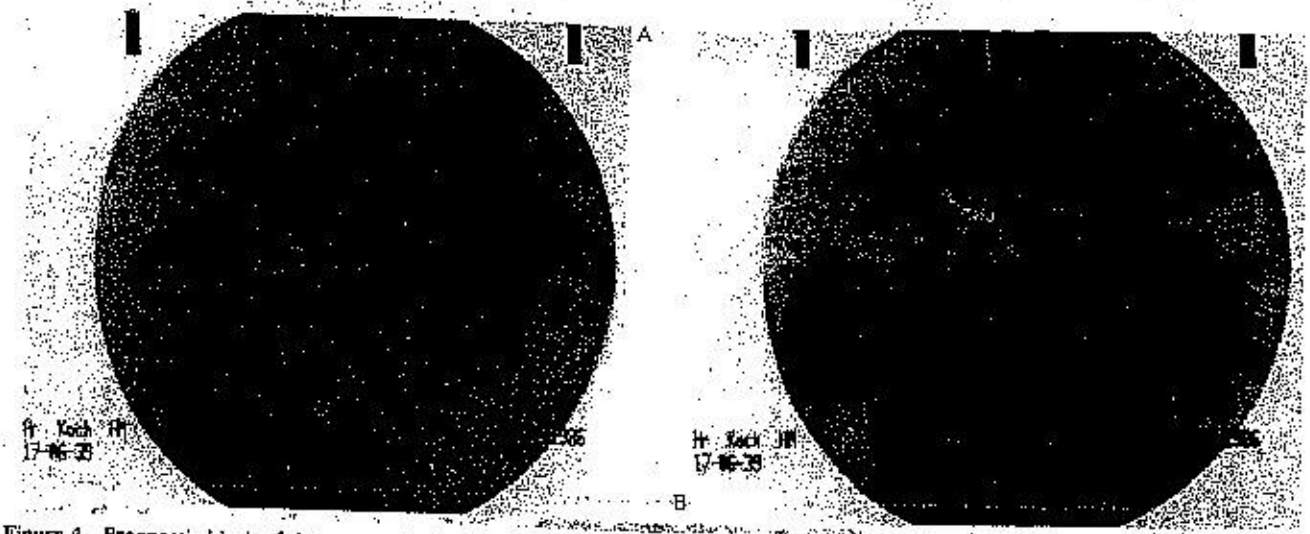

Figure 4 Prognostic block of the communicating ramus. A: Transverse projection; B: A–P projection.

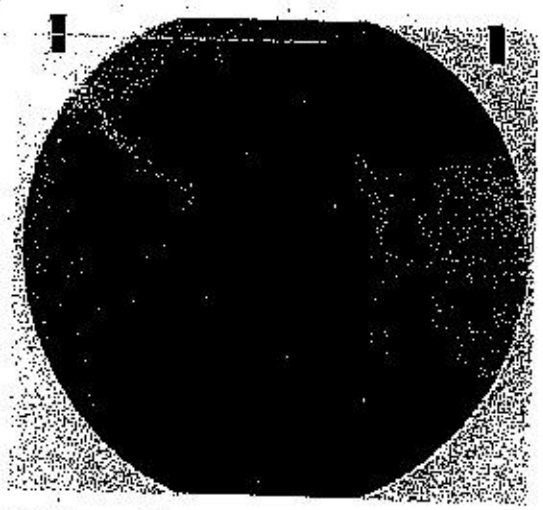

Figure 5 Prognostic block of the S1 segmental nerve.

Instrumentation and technique for a radiofrequency lesion

When making a radiofrequency lesion the sequence is always as follows:

1. Radiological positioning of the electrode.
2. Measurement of impedance to detect faulty cables or a short circuit.
3. Electrostimulation at a 50 Hz frequency to evoke a sensory response. This should confirm that the electrode is close enough to the target structure to make an effective lesion.
4. Electrostimulation at a 2 Hz frequency to evoke a motor response. This should confirm that the electrode is at sufficient distance from any motor fibres that might be damaged.
5. Readjustment of the electrode position if the results of electrostimulation are unsatisfactory, followed by 3, etc.
6. Injection of local anaesthetic solution through the outer cannula.
7. Creating a temperature-controlled lesion.

As can be deduced, the use of electrostimulation is critical both for the effectiveness and for the safety of the lesion. It is therefore important to use a fine instrument which can be introduced and positioned without prior infiltration of the area with local anaesthetic solution.

The Radionics SMK system[14] is suitable to use. It consists of a 22G disposable cannula with stylet and a matching radiofrequency probe. Once the cannula is positioned the stylet is removed and replaced by the temperature-measuring radiofrequency probe. The system is available in 5, 10 and 15 cm lengths. The cannula of the 15 cm system is 20G in diameter.

Procedures

PERCUTANEOUS FACET DENERVATION

This is the best-known radiofrequency procedure for back pain. The groove between the superior articular and transverse processes is best visualized in a 10° oblique projection. SMK 10 cannulae are introduced in the direction of the beam and the position is checked on the transverse projection (Figure 6). After electrostimulation and injection of local anaesthetic a 80°C lesion is made.

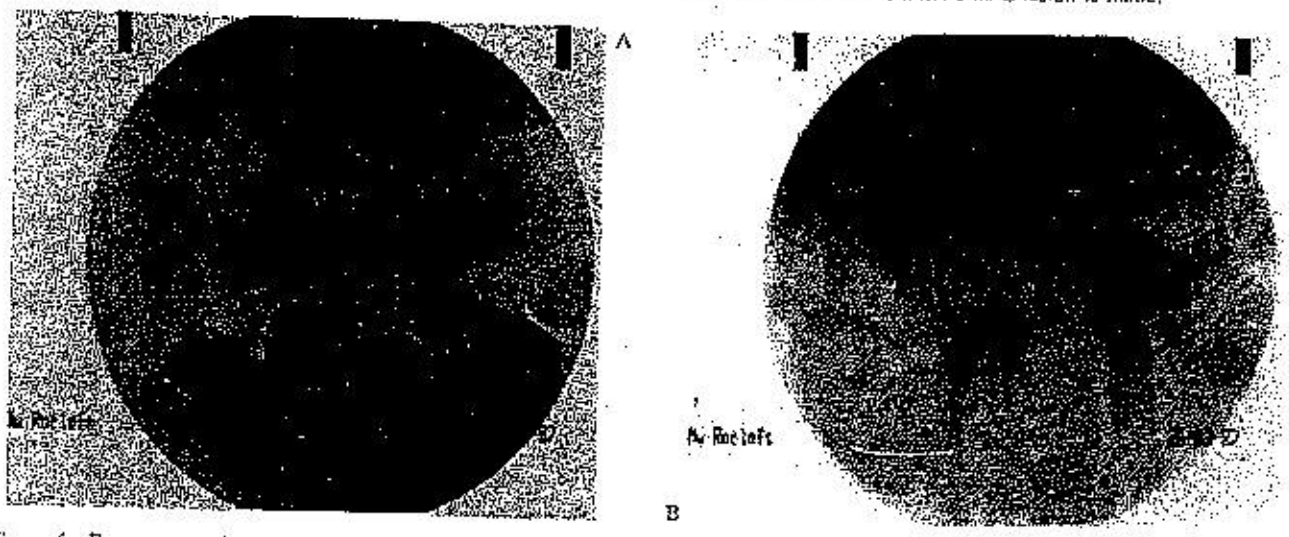

Figure 6 Percutaneous facet denervation. A: Ten-degree oblique projection; B: transverse projection.

There is no sensory loss after this procedure and there is practically no morbidity. The author has not recorded any complications in a series of well over 2000 cases.

THE COMMUNICATING RAMUS

Since this procedure is mentioned here for the first time the technique will be described more extensively.

Prognostic blocking

A 20° oblique projection is used for this procedure. In this projection the posterior joints are projected away from the posterolateral aspect of the vertebral body. An entry point is selected overlying the lateral border of the vertebral body just caudal to the transverse process. A 15 cm needle is introduced for approximately 5 cm in the direction of the beam and the proper direction is checked. Corrections of the direction should be made at this stage rather than in the deeper layers, where accidental contact might be made with the segmental nerve. The needle is carefully further introduced to make contact with the lateral border of the vertebral body. The position is then checked on the transverse projection, where the tip should lie just anterior to the intervertebral foramen.

A water-soluble contrast (0.5 ml) is now injected. This should show the relevant tissue space as a line running anteriorly on the transverse projection and as a dot on the AP projection (Figure 4).

Radiofrequency procedure

The electrode is positioned as described for the prognostic block. As soon as contact with bone is made electrostimulation is carried out. The object is to find a position where the patient reports tingling or even pain in the back at a voltage <1.5 V, while motor stimulation is negative up to 3 V. In this first position these criteria are met in 35% of patients.

If the patient reports tingling in the leg instead of in the back, and motor stimulation is positive, the electrode is displaced slightly laterally until it just slides off the vertebral body. Further movements are stopped as soon as this is felt to happen, and electrostimulation is repeated. If the criteria are still not met the cannula is gradually moved forward, mm for mm, each time carrying out electrostimulation.

As soon as a satisfactory position is found local anaesthetic solution is injected and a 60 s 80°C lesion is made. A typical electrode position is shown in Figure 7. In an exceptional case it is not possible to find a satisfactory position in this way. If this happens a second cannula is introduced exactly parallel to the first one, and 5 mm more caudal, and the same sequence is followed. If again no satisfactory position is found the area is traversed with the two electrodes kept at the same anteroposterior level and with one of the electrodes serving as a ground. This can easily be done by inserting the stylet and leaving it sticking out for 2 cm for attaching an ordinary wire with crocodile clamp for connection to the ground entrance of the lesion generator. In some patients a satisfactory position can now be found, and a lesion is made with the same configuration.

After this procedure there is no sensory loss and there is no sympathetic block. Postoperative morbidity is usually more pronounced than after a facet denervation. Roughly 30% of patients complain of increased pain in the back, or exceptionally in the leg, for as long as 2–3 weeks. Otherwise no complications have been observed in a series of 118 cases.

RADIOFREQUENCY SYMPATHETIC BLOCK

This block was the first radiofrequency procedure in the treatment of mechanical back pain emanating from the anterior compartment. The procedure has few indications since the advent of the communicating ramus lesion, which is usually just as effective and which so far has a lower complication rate. Some patients remain, however, who do not react to a communicating ramus block at one level and who are completely relieved by a sympathetic block. The sympathetic block which results from this procedure is in fact an

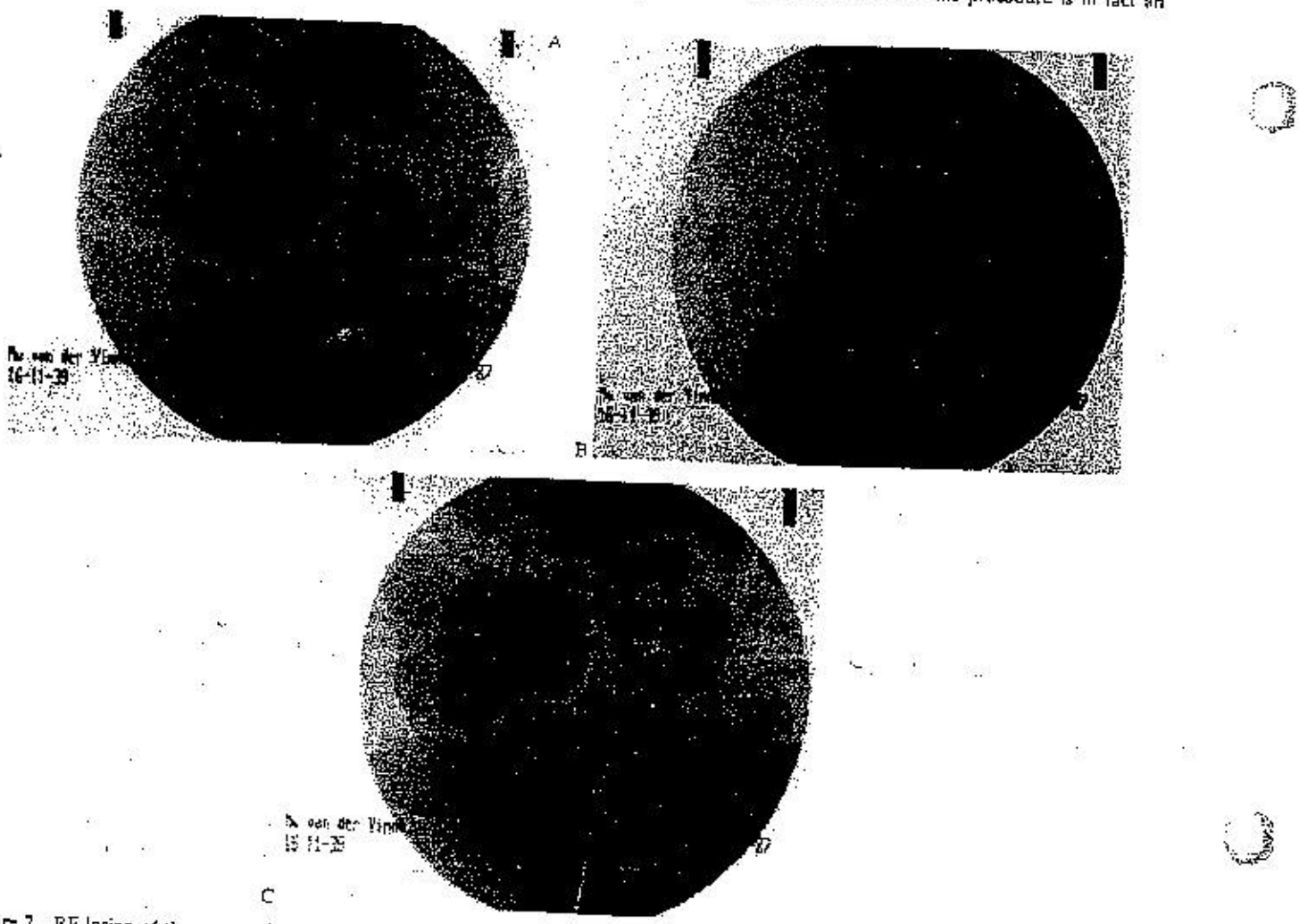

Figure 7 RF lesion of the communicating ramus. A: Twenty-degree oblique projection; B: transverse projection; C: A–P projection.

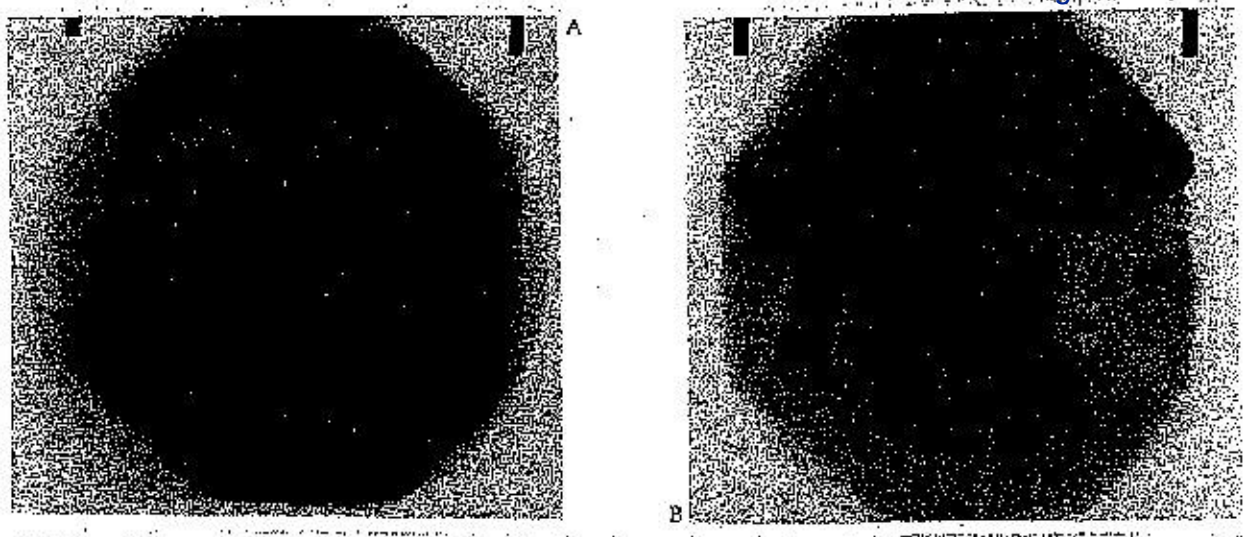

Figure 8 Percutaneous partial rhizotomy L4. A: AoP projection; B: transverse projection.

unavoidable and sometimes troublesome by-product. There seems to be no detectable relationship between the degree of sympathetic block and the result in terms of pain relief after this procedure.

A sympathetic block for vascular insufficiency is usually done at the L2–L3 level, since it is here that the complete sympathetic outflow passes. The afferent fibres from the anterior part of the annulus, however, do not travel upwards before entering the spinal canal. A radiofrequency sympathetic block for relief of low back pain should therefore be done at the painful level, usually L4–L5.

SMK 15 cannulae are introduced at these levels in the direction of the beam using a 20° oblique projection. When using this approach it is easy to avoid painful contact with the periosteum of the vertebral body. The proper position is checked by injecting a water-soluble contrast, and 80°C lesions are made.

There is usually very little morbidity after this procedure. The main complication is an overshoot of the sympathetic block, resulting in a hot, swollen and sometimes even hyperaesthetic leg. This usually subsides in a matter of weeks without further treatment, but in 1–2% of all cases these distressing symptoms may persist for as long as 8 months.

PERCUTANEOUS PARTIAL RHIZOTOMY

If all prognostic blocks of the mechanical components are negative, and if the patient has predominantly leg pain, the segmental nerves may be blocked consecutively to determine whether a patient might possibly benefit from this procedure. It should only be performed if one block is completely positive, whereas a block of the adjoining roots is negative. It is helpful to carry out electrostimulation before injecting the local anaesthetic solution. The spread of contrast should be closely watched, since accidental spread into the epidural space may easily cause a block to be falsely positive.

An L4 or L5 partial rhizotomy is performed with a SMK 10 system from a lateral approach. The transverse process is contacted and the cannula is then manoeuvred to enter the cranial and dorsal part of the foramen, where the ganglion is located (Figure 8). Electrostimulation is carried out which should elicit sensory response below 1 V and a motor response not below twice the sensory threshold. A 65–70°C lesion is made depending on the sensory threshold.

For S1 and S2 it is not possible to reach the ganglion with a straight instrument. The nerve should be visualized as for a prognostic block. The S1 ganglion is situated halfway between the S1 foramen and the cranial border of the sacrum, the S2 ganglion halfway between foramina S1 and S2. Next a small drill-hole is made over this location with a small pneumatic drill as is used in maxillary surgery, connected to a fine Kirschner wire. The proper direction is checked by monitoring a 10° oblique projection in opposite directions. This projects the tip of the wire away from the nerve. The two oblique projections should show symmetrical images (Figure 9). As soon as the wire is felt to enter the sacral canal it is withdrawn and replaced by a special electrode (Radionics SRK). Electrostimulation and lesioning parameters are identical to the L4/L5 procedure.

There is either slight hypaesthesia of the relevant dermatome after a partial rhizotomy or there is no sensory loss at all. In 30% of all cases there is a neuritis-like reaction with pain and hyperaesthesia. This usually becomes manifest on the 5th postoperative day and may last for 4–8 weeks, then subsiding without further treatment. The only long-term complication is a hypaesthesia which is too dense despite strict adherence to technical details. This happens in 2% of cases. This condition too usually recovers, but this may take as long as 12–18 months.

Results

Assessment of the results is difficult since there is a lack of objective criteria. For the moment the patient's own judgement seems to be the most reliable parameter. If success is defined as a better than 50% result a percutaneous facet denervation has a success rate of 40% as opposed to 80% in a virgin back. These figures are in reasonable agreement with other reports.[14–16] There is general agreement that the results are less favourable in the failed back patient, especially after a fusion.

The results of the lesion of the communicating ramus are preliminary. Follow-up was available in 20 failed back patients. Nine patients had undergone a laminectomy, two patients a fusion and the remaining nine patients had had multiple operations. Two patients had had pain for 2–5 years, the remaining cases for up to 20 years. The success rate was 60% as opposed to 70% in non-operated patients.

A percutaneous partial rhizotomy had a 40% success rate as opposed to 60% for the virgin back. These figures, although giving an indication of what to expect, fail to provide information on the proportion of patients who do not react on any prognostic block, and who therefore cannot be treated with radiofrequency lesions. Work is in progress to answer this question.

Discussion

A percutaneous facet denervation has so far been the only procedure available for the relief of mechanical back pain. Mechanical back pain may, however, emanate from all components of the three-joint complex, not just from the posterior joints. Kellgren[17] is of the opinion that further research on mechanical pain emanating from structures in the anterior compartment may yield information which is of equal importance to the discovery of the prolapsed disc. Jaffray and O'Brien[18] described an inflammatory reaction in tissue which was removed from the prevertebral region during anterior spinal fusion. Pathology of structures in the anterior compartment may be more important than has been generally accepted. The hopeful initial results of the communicating ramus procedure seem to confirm this view.

A wider range of radiofrequency lesions has now been developed. This improves the applicability of a form of treatment which has a number of attractive features. Radiofrequency lesions with modern electrode systems are well tolerated by most patients. Morbidity is acceptable. Other subsequent forms of treatment are not hampered in any way and the long-term complication rate is low.

Fears for adverse effects of deafferentating procedures do not seem justified. The only procedure which theoretically completely denervates a structure in the back is a facet denervation. Experience

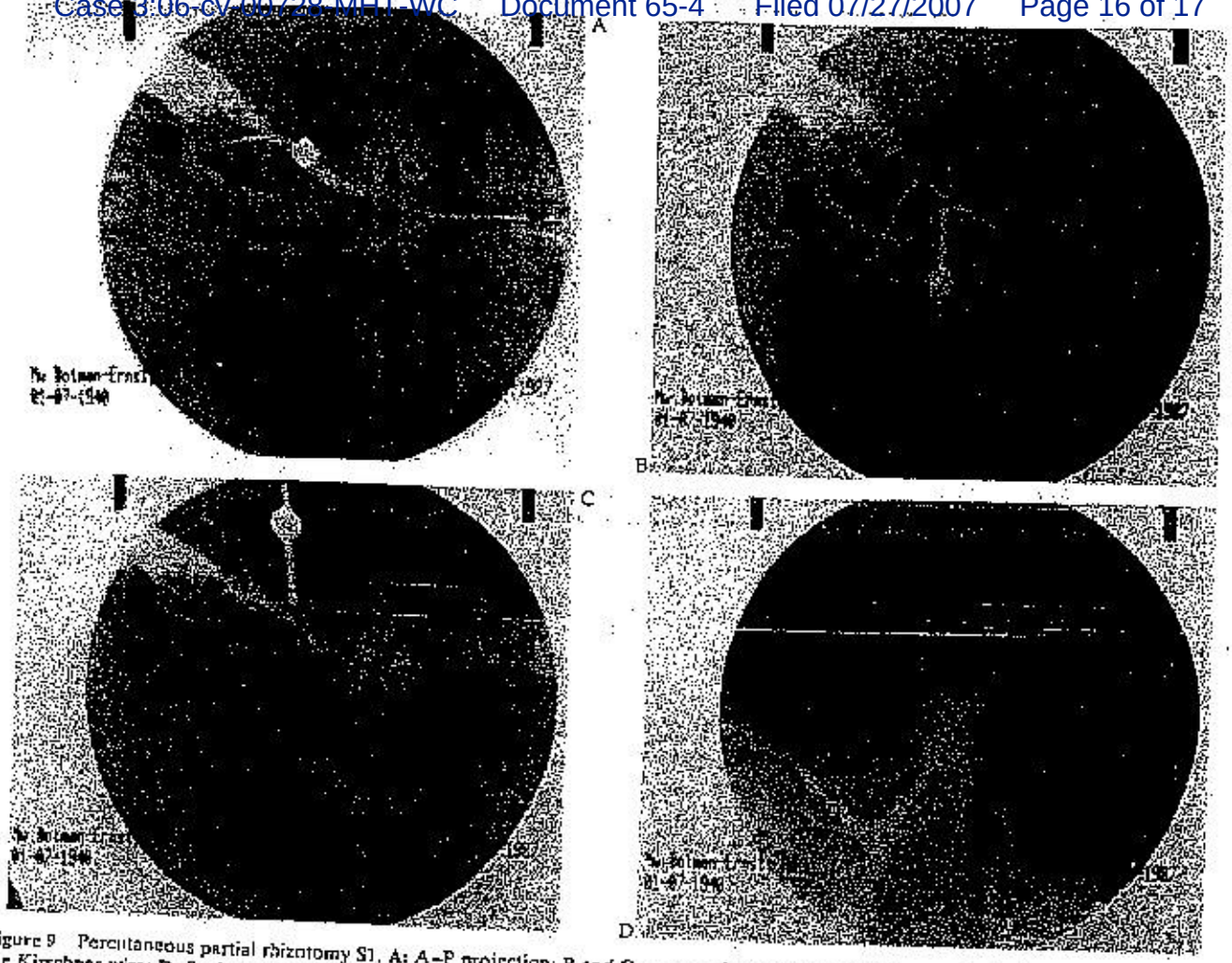

Figure 9 Percutaneous partial rhizotomy S1. A: A–P projection; B and C: symmetrical oblique projections to check the proper direction of the Kirschner wire; D: final position of the electrode on a transverse projection. The arrow points at the tip of the electrode inside the sacral canal.

with this procedure has accumulated for over 15 years. Long-term deleterious effects have never been described. Otherwise there is no sensory loss after any of the procedures intended to relieve mechanical back pain. The risk of creating a deafferentation syndrome exists only after a partial rhizotomy. This is fully realized when performing this procedure. Sensory loss after a successful partial rhizotomy is minimal and usually temporary. Indeed the whole idea of making a partial lesion of the dorsal root ganglion emanates from the knowledge that a complete interruption would be deleterious, since afferent input is indispensable for maintaining an equilibrium in the dorsal horn.

The main disadvantage of the method is that it may take some patience and endurance, both from the patient and from the doctor, to go through all the prognostic blocks, possibly followed by one or even several procedures. The patient often does not expect this, since he is usually of the opinion that there is one single cause for his pain, that this cause is anatomically demonstrable and that one single treatment will eliminate stimuli from this source once and for all. This, of course, is wrong on all counts and careful education of the patient is therefore essential.

As for the results it should be taken into account that we are dealing with a group of patients in whom all other modalities of treatment have failed. It may be argued that the success rates are modest and that a placebo response should be taken into account. Since radiofrequency lesions are an invasive method it does not seem justified to compare the result to a control series. There are, however, several arguments which make a placebo response most unlikely. These patients have all had pain for a long period of time and they have been subjected to many forms of treatment. They have all had a series of prognostic blocks, which had an effect not exceeding the duration of action of the local anaesthetic. After the radiofrequency lesion many of them go through a period of discomfort before the improvement becomes manifest.

The success rates would probably have been better if more sophisticated selection methods had been available. A low success rate in fact only means that there is a discrepancy between the result of prognostic blocking and the result of the following radiofrequency lesion. This may be due to several factors. As already mentioned, prognostic blocking is not an ideal and unfailing method, it is just the best we have so far. There may also be technical failures of the radiofrequency lesion, since there is no way of testing whether or not a satisfactory interruption has been made. Finally psychological factors may be involved. It is also difficult to say why this discrepancy tends to be more pronounced in failed back patients. This may well mean that pain in these patients is more often multifocal so that the fallacies of prognostic blocking become more manifest. Psychological factors might also be more prominent.

After a successful treatment with radiofrequency lesions pain may recur. It is in fact surprising that this only happens in a minority of patients. Most radiofrequency lesions in back pain are used to interrupt peripheral nerve fibres. Since the cell bodies of these fibres remain unharmed, and the lesions do not create much anatomical upset, these fibres may regenerate. Radiofrequency lesions are therefore more like a nerve block with a very prolonged action. Recurrence of pain may be an inconvenience but it does not make this form of treatment less valuable. The duration of action of the block may be used to give conservative measures a better opportunity. If this is still insufficient there is always the possibility of repeating the procedure.

In summary, this form of treatment may be considered if other modalities have no more to offer. It is well tolerated, it has few adverse effects and it has a measure of success. The potential has been widened in recent years since new technology has permitted the development of new techniques. Nevertheless radiofrequency lesions, like any other form of treatment, are not a panacea for the failed back patient.

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